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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,791	11/14/2003	Stefan Willmann	Bayer 10263-WCG	2985
27386 7590 10/31/2007 NORRIS, MCLAUGHLIN & MARCUS, P.A. 875 THIRD AVE 18TH FLOOR NEW YORK, NY 10022			EXAMINER ZEMAN, MARY K	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 10/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/714,791

Applicant(s)

WILLMANN ET AL.

Examiner

Mary K. Zeman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group II, claims 10-18 in the reply filed on 7/26/07 is acknowledged. The requirement is withdrawn. All claims are examined herein.

Claims 1-27 are pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The IDS filed 4/30/04 has been entered and considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1-9 are drawn to computer “systems” which lack any tangible embodiments. Each of the “modules” may exist in software alone. The method steps performed by the system “for predicting” profiles or parameters are not a concrete tangible and useful result. Incorporation of limitations to physical system elements, and a concrete, tangible and useful result may overcome this rejection. Claims 10-19 are drawn to methods which do not provide a physical transformation of matter, nor do they provide a concrete, tangible and useful result. The result of the method of claim 10 is a “simulation” which is not output (tangible), is not clearly obtained in all cases (concrete), and is not immediately useful. The “simulation” requires further manipulation and interpretation to be

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used. Claims 19-27 are drawn to digital storage media which carry out a method which is non-statutory. Further, there is not limiting definition of “digital storage media” such that the term can be broadly construed to cover non-statutory storage media such as carrier waves and wireless storage.

For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomenon. *Diehr*, 450 U.S. at 187, 209 USPQ at 8 (“application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”); *Benson*, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it “has no substantial practical application”).

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

- 1) The claimed invention “transforms” an article or physical object to a different state or thing.
- 2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation “is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application.” *AT&T*, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a “practical application,” the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is “useful, tangible and concrete.” (1) “USEFUL RESULT” For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO’s official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and *Fisher*, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of “specific” and “substantial”). (2) “TANGIBLE RESULT” The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. *Benson*, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had “no substantial practical application.”). “[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection.” *Diehr*, 450 U.S. at 187, 209 USPQ

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at 8 (emphasis added); see also *Corning*, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 (“It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .”). In other words, the opposite meaning of “tangible” is “abstract.” (3) “CONCRETE RESULT” Another consideration is whether the invention produces a “concrete” result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In *re Swartz*, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is “irreproducible” claim should be rejected under section 101). The opposite of “concrete” is unrepeatable or unpredictable.

See also: 1300 OG 142, 11/22/2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, (and 10 and 19,) the metes and bounds of the limitations of the modules are unclear. The claim refers to element 102, which is a box in figure 1, totally lacking in any description as to what the model encompasses. The specification at page 4 fails to provide a specific definition of the model and says it “involves physiological parameters which depend only on the type of insect to be described as well as one or more substance-dependent parameters.” The specification page 6 discloses further information about a model with reference to Figure 3, which does not set forth element 102. it is entirely unclear what parameters are to be used and how the parameters are to depend on the substance. Further, the prediction module is similarly indefinite as the specification is totally lacking in the elements of such a module of 110. How a single substance –based- parameter can drive a simulation and

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prediction according to the claim is not set forth in positive active steps in the claim nor the specification. It is further unclear in description of “a parameter”. It would appear the system already has the parameter that is to be predicted, which is circular and indefinite.

Claims 2-5 fail to remedy the deficiencies in claim 1. claim 6 is unclear, as it is not clearly set forth where the QSAR model or neural network are to be placed in the system of claim 1. In claim 7, it is entirely unclear how the prediction module is to be “based on” a database (108) which lacks in detail. Claims 8 and 9 fail to remedy the deficiencies of claim 1.

Claims 10 and 19 are structurally similar in setup to claim 1 and have similar deficiencies. Claim 10 fails to set forth positive active steps by which the methods is to be specifically performed. Claims 11-18 and 20-27 do not remedy these problems.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Keane.

The claims are drawn to systems, methods and software for predicting pharmacokinetic properties of a substance, through the use of compartmentalized insect models. Various parameters of the substance can be used. Intercompartmental mass transport is a particular parameter, as is equilibration, distribution coefficients, MW, solubility etc.

KEANE (US 2002/0002447, having priority to at least 7.13.1999) discloses use of compartmentalized models to estimate pharmaceutical and/or kinetic parameters of chemicals and compositions. Keane specifically discloses parasites, which can include some types of insects. Databases of known effects and PK data of known chemicals are assembled, and simulations or models of the multiple compartments are assembled and/or trained. This information is used to estimate or predict behavior of the substance in the model organism. Mass transport equations are specifically disclosed, as are fluid dynamic parameters such as distribution coefficients, MW, solubility and equilibrium. Section 0268+ discloses interfaces to organ models which can include absorption, lipophilicity, etc.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjie Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

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Handwritten:
10/24/07
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Primary Examiner